

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/766,638	HOLMES-FARLEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Humera N. Sheikh	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 05 July 2005.
2. ☒ The allowed claim(s) is/are 1 and 3-15.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                                     |                                                                                       |
|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)                                                    | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|                                                                                                                     | 9. <input checked="" type="checkbox"/> Other <u>See Continuation Sheet</u> .          |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Amendment after Non-Final Office Action, Applicant's Arguments/Remarks, the Terminal Disclaimer and the request for extension of time (3 months-granted), all filed 07/05/05 is acknowledged.

The 35 U.S.C. §101 statutory-type double patenting rejection of claim 1 has been withdrawn, by virtue of Applicant's amendment filed 07/05/05. The non-statutory obviousness-type double patenting rejection of claims 1-15 has been withdrawn, by virtue of Applicant's submission of a Terminal Disclaimer filed 07/05/05.

Claims 1 and 3-15 are pending. Claims 1 and 3 have been amended. Claim 2 has been cancelled. Claims 1 and 3-15 are allowed.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 07/05/05 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of Patent No. 6,509,013 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Allowable Subject Matter***

Claims 1 and 3-15 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art does not disclose nor fairly suggest the instant pharmaceutical composition comprising a carrier and a crosslinked, water insoluble polyallylamine homopolymer, wherein said polyallylamine homopolymer comprises repeat units represented by the formula depicted in claim 1, wherein  $n$  is an integer, wherein said polyallylamine homopolymer is crosslinked with an epichlorohydrin crosslinking agent, and wherein the homopolymer is fully protonated, partially protonated or unprotonated. The instant invention demonstrates superior results because it provides for improved phosphate binders, which can be administered orally in acceptable dosage levels without resulting in many serious side effects. The invention provides for an effective treatment for decreasing the serum level of phosphate by binding phosphate in the gastrointestinal tract, without concomitantly increasing the absorption of any clinically undesirable materials, particularly calcium or aluminum.

- In Applicant's response filed 07/05/05, Applicants have amended instant claim 1 to include the instant claim 2 limitation 'wherein said polyallylamine homopolymer is crosslinked with an epichlorohydrin crosslinking agent', which overcomes the 35 U.S.C. §101 statutory-type double patenting rejection of claim 1. Additionally, Applicants have submitted a Terminal Disclaimer (filed 07/05/05) to obviate the non-statutory obviousness-type double patenting rejection of claims 1-15. Accordingly, all outstanding rejections have been withdrawn. This application is now in proper condition for allowance, rendering it non-obvious and patentable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 


Patent Examiner

Art Unit 1615

August 31, 2005

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Continuation of Attachment(s) 9. Other: Acknowledgement is made of the drawings filed 1/28/04. The drawings are accepted by the Examiner.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 2000